V. 3390

No. 20995

IN THE

United States

Court of Appeals

For the Ninth Circuit

GLYNN RICHARD DAVIS and
FLORENCE DAVIS, husband and wife,
Appellants,

v.

WYETH LABORATORIES, INC., a New York Corporation, and AMERICAN HOME PRODUCTS CORPORATION, a Delaware corporation,
Appellees.

APPELLANTS' BRIEF

Appeal from the U. S. District Court
for the District of Idaho

HONORABLE FRED M. TAYLOR, *Judge*

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SUBJECT INDEX

INDEX OF CASES AND AUTHORITIES

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STATEMENT OF JURISDICTION OF UNITED STATES DISTRICT COURT

This is an appeal by Glynn Richard Davis and Florence Davis, husband and wife, from a Judgment entered pursuant to a jury verdict dated January 29, 1966, by the United States District Court for the Dis-

trict of Idaho, Southern Division. The cause came on for trial before the Court and a jury on January 18, 1966. Federal jurisdiction is predicated on diversity of citizenship and the required statutory claim in excess of the sum of $10,000.00, exclusive of costs and interest. Jurisdictional facts were admitted and appeared to the Court to exist, pursuant to the Pre-Trial Order.

JURISDICTION OF COURT OF APPEALS FOR NINTH CIRCUIT TO HEAR THE APPEAL

Judgment was entered in the above-entitled action on the 28th day of January, 1966. Notice of Appeal was filed on the 14th day of February, 1966, pursuant to Title 28 U.S.C.A., Federal Rules of Civil Procedure, Rule 73(a).

APPELLANTS' STATEMENTS OF THE CASE

The Defendant, Wyeth Laboratories, a division of American Home Products, produces a product known as Sabin Oral Polio Vaccine, Type III. (P. 46, lines 10-15) Live polio virus are contained in this vaccine. (P. 446, Line 20—P. 446, line 9) Acute anterior poliomyelitis is caused by a virus which enters the human host through the mouth. Multiplication of the virus occurs in the gastrointestinal trace (P.471, lines 1-5) Medical science is unable to explain how the virus is transmitted to the anterior horn cells. Nevertheless, the virus does effect these anterior horn cells and produces the paralysis commonly referred to as polio.

During the early 1950s, the United States was faced with an outbreak of polio which took on epidemic pro-

portions. The Salk Vaccine was introduced in the early 1950s.

Salk Vaccine consists of killed polio virus. This vaccine is introduced into the human host by means of a hypodermic needle. After 1955, the Salk Vaccine was considered 100% safe. (P. 377, lines 3-6; P. 656, lines 13-15). Polio incidence continued to show a rapid decline from the introduction of the Salk Vaccine to the present date.

Clinical testing of the Sabin Vaccine commenced in the United States between 1960 and 1961. (P 581 lines 11-13) This vaccine is a live virus. (P 602, line 9 - P. 603, line 9) Supposedly it is weakened to the point that it can produce immunity but will not produce the disease itself. (P. 603, lines 6-9) The Sabin Vaccine is introduced into the human host by means of drops which are placed on a sugar cube and taken orally (Defendant's Exhibit No. 40) Shortly after the Sabin Vaccine appeared on the market, cases of paralytic polio occurring within thirty days of the administration of the vaccine began to appear. (Defendant's Exhibit 51; P. 356, lines 5-14) The Surgeon General of the United States, alarmed by this discovery, convened a special advisory committee, consisting of the leading specialists in the field of polio in the United States, to inquire into this phenomenon. (P. 355, lines 12-23) The committee determined that there was a causal connection between the vaccine and the resulting cases. (Defendant's Exhibits No. 40 and 51; P. 359, lines 20 - P. 360, line 1; P. 361, lines 21-24; P. 362, lines 12-13; P. 363, lines 10-18) This committee met five times during

1962. (P. 356, line 14) During the course of that year, they recommended that the Type III oral polio vaccine should not be administered to adults. (P. 359, lines 23-25)

The United States Government licensed the sale of oral Type III vaccine in March 1962. (P. 447, lines 1-3) Some difficulty was encountered prior to the licensing. (P. 446, lines 19-25; P. 447, lines 1-4) Three drug companies produced the oral vaccine, to-wit: Phiser, Wyeth and Lederle.

This particular case is concerned with the administration of the oral type III vaccine to Glynn Richard Davis, the Plaintiff, in West Yellowstone, Montana, during the month of March in 1963. (P. 167, lines 10-12; P. 127, lines 7-16; P. 128, lines 9-10) The history behind the mass immunization program held in eastern Idaho and West Yellowstone, Montana, is particularly important in this case. James Franklin was a territory manager for the Defendant, Wyeth Laboratories, Inc., in eastern Idaho in the year 1963. (P. 44, lines 2-4) He had been employed by Wyeth for some nine years. (P. 44, line4) Prior to 1963, the town of West Yellowstone, Montana had been a part of his territory. (P. 45, lines 3-4) However, in 1962, this community was dropped because it did not have any licensed physicians. (P. 45, lines 8-10) In October of 1962, the Wyeth drug company sent Mr. Franklin to Nevada where he observed a mass immunization clinic. (P. 76, lines 16-25) The purpose of this trip was to train Mr. Franklin in the procedures used at the clinic and to instruct him concerning the advertising necessary for a program of

this magnitude. (P. 77, lines 1-12) The Nevada clinic utilized The Denver Book produced by the Wyeth drug company in setting up its mass immunization clinics. (P. 77, lines 20-22) The medical society in eastern Idaho became interested in the Sabin oral vaccine. (P. 87, lines 6-11) After meeting with representatives from Wyeth, Lederle and Phiser, the medical society decided to go forward with a mass immunization program utilizing the Wyeth product. (P. 87, lines 24-25) The defendants in this case have constantly tried to place the blame on the medical society for failing to warn the public of the risk involved in taking the Sabin Oral Type III Vaccine. Their defense has been that Mr. Franklin merely sold the product to the medical society and thereafter had very little to do with the program. The testimony of Mr. Franklin is to the contrary.

After the medical society selected the Wyeth company's product, Mr. Franklin was actively engaged in promoting his company's product to the public. (P. 46, lines 16-18; P. 49, lines 11-17; P. 55, lines 16-18; P. 56, lines 2-6; P. 59, lines 3-22; P. 60, lines 19-25; P. 61, line 1; P. 115. lines 3-6; P. 116, lines 15-19; P. 169, lines 1-25; P. 170, lines 20-22; P. 202, lines 8-11; P. 248, lines 20-25; P. 250, lines 1-2; P. 259, lines 18-22; P. 261, lines 13-15; P. 265, lines 1-5)

It was Mr. Franklin who came to the Idaho medical society and asked that the city of West Yellowstone, Montana, be included in the Idaho program. (P. 776, line 24 - P. 777, line 2) It was Mr. Franklin who delivered books on how to conduct a mass immunization clinic to the advertising agency and the medical society.

(P. 46, lines 14-15; P. 49, lines 15-17) It was Mr. Franklin who took care of the details of delivering the vaccine to West Yellowstone. (P. 59, lines 3-5; P. 57, lines 4-8; P. 60, lines 19-20) It was Mr. Franklin who prepared the necessary documents along with the vaccine and shipped them to West Yellowstone. (P. 80, lines 2-11; P. 116, lines 15-24) These documents included advertising posters, consent forms, tally sheets and various other paraphernalia essential to the conducting of a mass immunization program. Mr. Franklin was instructed by his company to drop everything else and to work on the mass immunization clinics. (P. 202, lines 8-11)

In March of 1963, the Plaintiff, Glynn Richard Davis, resided in West Yellowstone, Montana. The population of West Yellowstone was not over 300 people. (P. 124, line 14) The Plaintiff was a strapping six-footer engaged in the lumber business. (P. 124, lines 10-11; P. 123, line 17) He was employed as a millwright at the Elk Stud Lumber Company. (P. 123, line 17) His physical condition was excellent. (P. 122, lines 23-24) The community of West Yellowstone is relatively isolated during the winter months. (P. 125, lines 20-21; P. 124, lines 16-19) Temperatures often drop below the -40° level. (P. 126, line 19)

Davis became aware of the "K-O polio" program through the various advertising media. (P. 125, lines 8-21) He observed posters which had been placed at strategic locations around the town. (P. 126, lines 4-5; P. 126, lines 16-21) Davis felt it was his civic responsibility to take the oral vaccine in an attempt to completely

stamp out the dreaded disease of polio. (P. 146, line 23—P. 147, line 5) He took the Defendant's product on March 19, 1963. (P. 167, lines 11-12) Within three weeks he was paralyzed from the waist down and has been ever since. (P. 133, lines 11-25) Davis' condition has been diagnosed by various physicians as acute anterior poliomyelitis. (P. 194, lines 3-5; P. 316, lines 2-3; P. 442, lines 16-17; P. 514, lines 2-4)

Davis at no time was advised that there was any risk in taking the Sabin Type III Vaccine. (P. 125, lines 22-24) The posters which had been sent to West Yellowstone by the Defendant's agent did not contain any warning of the risk involved. It is interesting to note that the first knowledge that the Defendant's agent, Mr. Franklin, had of the risk involved came to him through a newspaper article. The company did not send Mr. Franklin any notice of the risk involved. (P. 62, lines 13-19)

The Wyeth drug company was notified of the risk involved in taking the Type III vaccine. Doctor Bierly testified that there is an association between the vaccine and the disease epidemiologically. (P. 606, lines 12-14) This information was communicated to the Wyeth Laboratories in September of 1962. (P. 609, lines 11-15)

The risk involved in taking the Type III vaccine is grossly misleading on a statistical basis. Evidence was introduced that the risk in taking the Type III vaccine was somewhere in the neighborhood of one in one million. Doctor Ernest Ager and Doctor Riemert Ravenholt both testified that the risk factor must be considered

in relation to the individual's age, background, sex, and socioeconomic grouping. The Surgeon General's committee found that the risk is much higher for people above thirty years of age who lived in rural areas. It also found that the risk was higher in males than in females. Doctor Ravenholt testified that there was a particularly susceptible group located in the Pacific Northwest.

It is the position of the Plaintiff that there was sufficient evidence to go to the jury on the issue of failure to warn, absolute liability, res ipsa loquitur negligence in manufacture, and implied warranty. This case was submitted to the jury solely on the issue of implied warranty. (P. 922, lines 2-10; P. 923, lines 3-5; Instruction No. 13, P. 938; Instruction No. 14, P. 940) The Court granted Defendant's Motion pursuant to Rule 50 of the Federal Rules of Civil Procedure as to all causes of action save and except implied warranty. (P. 903, lines 19-20; P. 922, lines 2-10; P. 923, lines 3-5)

SPECIFICATION OF ERROR NO. 1

The District Court erred in refusing to instruct the jury on the doctrine of absolute liability and in taking said cause from the jury. (P. 907, lines 14-16)

POINTS AND AUTHORITIES IN SUPPORT OF SPECIFICATION OF ERROR NO. 1

In *Greenman v. Yuba Power Products, Inc.*, 377 P. 2d 897 (Cal. 1963), the California Supreme Court enunciated a reasonable doctrine fitted to commercial practices and the realities of modern day society.

"A Manufacturer is strictly liable in tort when an article he places on market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being. Recognized first in the case of unwholesome food products, such liability has now been extended to a variety of other products that create as great or greater hazards if defective. (citations omitted) Although in these cases strict liability has usually been based on the theory of expressed or implied warranty, running from the manufacturer to the plaintiff, the abandonment of the requirement of a contract between them, the recognition that the liability is not assumed by agreement but imposed by law (citations omitted), and the refusal to permit the manufacturer to define the scope of its own responsibility for defective products (citations omitted) make clear that the liability is not one governed by the law of contract warranties, but by the law of strict liability of tort. Accordingly, rules defining and governing warranties that were developed to meet the needs of commercial transaction cannot properly be invoked to govern the manufacturer's liability to those injured by the defective products unless those rules also serve the purpose for which liability is imposed . . . The purpose of such liability is to insure that the cost of injuries resulting from defective products are borne by the manufacturers that put such products on the market, rather than by the injured persons who are powerless to protect themselves. Sales warranties serve this purpose fitfully at best."

In *Morrow v. Caloric Appliance Corp.*, 372 S.W. 2d 41 (Mo. 1963), the court stated:

> "Careful consideration of the recent decisions of the courts of other states to the same effect, the inclination of the courts of this state to modify the harsh results flowing from a rule of caveat emptor in analogous fact situations, the logic of the reasoning upon which these cases (and numerous other cases therein cited) are ruled in an effort to afford justice to the vast majority of the 'consumer' citizenry, whose well-being, health and very lives are dependent in great degree upon processed food and manufactured articles and facilities, the fitness or safe use of which the ordinary 'consumer' can know little or nothing other than the fact that the processor or manufacturer holds them out to the public as fit and reasonably safe for use by the 'consumer' when used in the manner and for the purpose for which they are manufactured and sold, lead inevitably to the conclusion that under the facts as found by the jury the appellant is to be held liable as an implied warrantor of the fitness and reasonable safety of the gas cooking range here involved, despite lack of privity of contract."

In *Goldberg v. Kollsman Instrument Corp.*, 191 N.E.2d 81 (N. Y.) the court stated:

> "A breach of warranty, it is now clear, is not only a violation of the sales contract out of which the warranty arises, but is a tortious wrong suable by a non-contracting party whose use of the war-

ranted article is within the reasonable contemplation of the vendor or manufacturer.

"As we all know, a number of courts outside of New York State have for the best of reasons dispensed with the privity requirements. Very recently the Supreme Court of California (*Greenman v. Yuba Power Products, Inc.*, 59 Cal.2d 67, 377 P.2d 897) (1963) in a unanimous opinion imposed 'strict tort liability' (surely a more accurate phrase) regardless of privity on a manufacturer in a case where a power tool threw a piece of wood at a user who was not a purchaser. The California court said that the purpose of such a holding is to see to it that the cost of injuries be borne by the manufacturer who put the product on the market, rather than by the injured person or persons who are powerless to protect themselves and that implicit in putting such articles on the market are representatives that they will safely do the job for which they were built."

In *Santor v. A & M Karagheusian, Inc.*, 44 New Jersey 52, 207 A.2d 305 (1965), the court stated:

"In this developing field of the law, courts have necessarily been proceeding step by step in their search for a stable principle which can stand on its own base as a permanent part of the substantive law. *The quest has found sound expression, we believe, in the doctrine of strict liability in tort* (emphasis added). Such doctrine stems from the reality of the relationship between manufacturers of products and the consuming public to whom the products

are offered for sale. As we indicated in Henningsen, the great mass of the purchasing public has neither adequate knowledge nor sufficient opportunity to determine if articles bought or used are defective. Obviously they must rely upon the skill, care and reputation of the maker. * * * It must be said, therefore, that when the manufacturer presents his goods to the public for sale he accompanies them with a representation that they are suitable and safe for the intended use. As the Supreme Court of California said, such representation must be regarded as implicit in their presence on the market. *Greenman v. Yuba Power Products, Inc., supra* (377 P.2d at 901). The obligation of the manufacturer thus becomes what in justice it ought to be—an enterprise liability, and one which should not depend upon the intricacies of the law of sales. The purpose of such liability is to insure that the cost of injuries or damage, either to the goods sold or to other property, resulting from defective products, is borne by the makers who put them in the channels of trade, rather than by the injured or damaged persons who ordinarily are powerless to protect themselves * * * *.

"As we have indicated, the strict liability in tort formulation of the nature of the manufacturer's burden to expected consumers of his product represents a sound solution to an ever-growing problem, and we accept it as applicable in this jurisdiction. And, although the doctrine has been applied principally in connection with personal injuries sustained by ex-

pected users from products which are dangerous when defective, . . . the responsibility of the maker should be no different where damage to the article sold or to other property of the consumer is involved (emphasis added) * * * *

"Under the strict liability in tort doctrine, as in the case of express or implied warranty of fitness or merchantability, proof of the manufacturer's negligence in the making or handling of the article is not required. If the article is defective, i.e., not reasonably fit for the ordinary purposes for which such articles are sold and used, and the defect arose out of the design or manufacture or while the article was in the control of the manufacturer, and it proximately causes injury or damage to the ultimate purchaser or reasonably expected consumer, liability exists. Existence of the defect means violation of the representation implicit in the presence of the article in the stream of trade that is suitable for the general purposes for which it is sold and for which such goods are generally appropriate. If it is not a fact—if the article is defective and the defect is chargeable to the manufacturer, his must be the responsibility for the consequent damage or injury. The liability does not depend on traditional requirements for proof of legal or equitable fraud. Considerations of good faith or innocence of the representation or wilfulness of the misrepresentation are immaterial to existence of the cause of action."

Oregon adopted the rule of absolute liability in *Wright's v. Staff Jennings, Inc.*, 405 P.2d 624 (Ore.

1965). The recent case of *Wright v. Massey Harris, Inc.*, 68 Ill. App.2d 70, 215 N.E.2d 465 (1966) adopts the rule of strict liability in tort.

The Idaho Supreme Court in *Bethlahmy v. Bechtel*, 415 P.2d 698 (Idaho 1966) adopted the language of *Shipper v. Levitt and Sons, Inc.*, 44 New Jersey 70, 207 A.2d 314. At page 708:

> "The law should be based on current concepts of what is right and just and the judiciary should be alert to the never ending need for keeping its common law principles abreast of the times. Ancient distinctions which make no sense in today's society and tend to discredit the law should be readily rejected * * *.
>
> "The arguments advanced by Levitt in opposition to the application of warranty or strict liability principles appear to us to lack substantial merit. Thus its contention that *caveat emptor* should be applied and the deed viewed as embodying all the rights and responsibilities of the parties disregards the realities of the situation. *Caveat emptor* developed when the buyer and seller were in an equal bargaining position and they could readily be expected to protect themselves in the deed. Buyers of mass produced development homes are not on an equal footing with the builder vendors and are no more able to protect themselves in the deed than are automobile purchasers in a position to protect themselves in the bill of sale. Levitt expresses the fear of 'uncertainty and chaos' if responsibility for de-

fective construction is continued after the builder vendor's delivery of the deed and its loss of control of the premises, but we fail to see why this should be anticipated or why it should materialize any more than in the products liability field where there has been no such result." 207 A.2d at 325-326.

SPECIFICATION OF ERROR NO. 2

The District Court erred in directing a verdict against appellants on the theory of res ipsa loquitur.

POINTS AND AUTHORITIES IN SUPPORT OF SPECIFICATION OF ERROR NO. 2

In one of the few cases concerning the Sabin vaccine, the doctrine of res ipsa loquitur was held applicable. The court stated in *Berry v. American Cyanamid Company*, 341 Fed.Rep.2d 14, Sixth Circuit, February, 1965, at page 20:

"Res ipsa loquitur is a rule of evidence. If applicable in this case, the plaintiff would make a prima facie case by introducing evidence that the taking of the vaccine caused the plaintiff to contract polio and that Lederle had exclusive control of the vaccine. The burden to proceed would then be upon Lederle to offer evidence on its behalf and in explanation of what caused the injury. However, the burden to prove negligence of Lederle by a preponderance of the evidence remains with the plaintiff.

"In dismissing count two of the complaint, the trial judge did not challenge the doctrine of res ipsa loquitur or its application in a products liability case

under proper circumstances. He dismissed it for the reason, as he stated, 'This Court, who has to make this determination as a matter of law, cannot say that there is any common experience or any ordinary course of events that teaches him that a person cannot contract polio from taking a polio vaccine, except for negligence of the defendant manufacturer.'

"We agree with the trial judge that the doctrine of res ipsa loquitur is based on a common or everyday experience. *Boykin v. Chase Bottling Works*, 32 Tenn.App. 508, 222 S.W.2d 889. The question presented by the dismissal of count two of the complaint is whether the trial judge was justified in saying there was no common experience relative to the use of polio vaccine.

It is a well known fact that during the early 1960s throughout the country and in the States of the Sixth Circuit a program was sponsored by physicians and health authorities advocating that everyone, children and adults, take Sabin oral polio vaccine. In many places mass production lines were set up by health authorities and the vaccine was administered without charge to those who availed themselves of the opportunity to take the vaccine. It was widely publicized that the disease of poliomyelitis could be virtually eliminated, if the mass of people, including children, would cooperate. It is now a known fact that the incidence of polio has been greatly reduced, if not almost entirely eliminated.

"We are of the opinion that there is a common experience relative to the use of Sabin oral vaccine,

as a result of the program of mass administration of the drug, to which reference is hereinabove made. Evidence of this experience should be available in the health department of any large city.

"We hereby remand the case to the District Court with instructions to take evidence on the experience in the use of Sabin oral vaccine and re-determine the validity of the second count of the complaint in the light of such evidence."

SPECIFICATION OF ERROR NO. 3

The court erred in directing a verdict pursuant to Rule 50 of the Federal Rules of Civil Procedure in favor of respondents on appellant's theory of failure to warn. (P. 923, lines 3-5)

POINTS AND AUTHORITIES IN SUPPORT OF SPECIFICATION OF ERROR NO. 3

In *Love v. Wolf*, 226 ACA 482, 38 Cal. Rptr. 183 (Cal. App. 1964) the manufacturer of cholormycetin attempted to hide behind its warning to the medical profession. The court held that the adequacy of the warning, even though it might comply with the warning required by the Food and Drug Administration, had to be considered in light of the fact that defendant's advertising *played down the danger*. Further, in this case, there was substantial evidence of over-promotion of the drug by the defendant's salesman which, if it induced the doctor to disregard warnings previously given, cancelled the warning. This statement by the court is

adequately expressed in the Journal of the American Medical Association, July 8, 1961, Vol. 177, No. 1, in an article written by Dr. Isaac Starr entitled "The Testing of New Dugs and Other Therapeutic Agents." The doctor states:

> "The doctor gets aid from the better grade pharmaceutical manufacturers who often distribute, with their new drugs, package inserts and brochures, which give an excellent description of the action, usefulness and dangers of their products. But too often this descriptive material contains statements and attitudes which lead one to suspect that the firm's advertising department, rather than their medical department, had the last word."

The defendants in this action in no way advised Mr. Brower, the pharmacist in West Yellowstone, that there was any danger involved in disseminating the vaccine. It is, therefore, plaintiffs' position that this vaccine was disseminated directly from Wyeth Laboratories, through their detail man James Franklin, to a druggist in West Yellowstone, Montana, who in turn administered the vaccine to the plaintiff. A warning, if any, to the doctors in Eastern Idaho certainly cannot be considered warning to a druggist in West Yellowstone, Montana. The defendants must either breathe hot or cold. If this is a prescription drug, it was not disseminated by or through a licensed physician. If it is not a prescription drug, no warning was disseminated to the public.

In the very recent case of *Stromsodt v. Parke-Davis and Company*, (N.D. 1966), 257 F.Supp 991, the court stated at page 997:

"Although all of the Government regulations and requirements had been satisfactorily met in the production and marketing of Quadrigen, the standards promulgated were minimal. The Defendant still owes a duty to warn of dangers of which it knew or should have known in the exercise of reasonable care. *Love v. Wolf*, 226 Cal.App.2d 378, 38 Cal.Rptr. 183. See also *Ebers v. General Chemical Co.*, 310 Mich 261. 17 N.W.2d 176; *Brown v. Globe Laboratories*, 165 Neb. 138, 84 N.W.2d 151; *Gonzalez v. Virginia-Carolina Chemical Company*, 239 F. Supp. 567 (DC, SC, 1965).

"The danger must be reasonably forseeable and the injury must be proximately caused by the failure to warn. The Defendant knew or should have known that Quadrigen might cause encephalopathies in some users and to warn of the danger.

"Though this may have been the first case in which encepholopathy occurred after the administration of Quadrigen, it does not preclude the finding of forseeability and negligence. See *Roberts v. United States*, 316 F.2d 489 (3 Cir., 1963)

"The warning 'Local reactions have been known to be more severe when the child is in the incubative stage of pertussis' on the insert accompanying the product, not only would not have warned members of the medical profession, but might have misled them to believe that only in cases where the child was in the incubative stage of pertussis would encephalitic symptoms occasionally occus.

"There is no competent evidence in the entire record, medical or otherwise, to show that Shane's condition arose out of or from any susceptibility or predisposition, nor that the child had any congenital disease or disorder or defect of any kind, nor that he had any allergy or diosyncrasy, nor that heredity was a factor that might account for his present condition."

SPECIFICATION OF ERROR NO. 4

The District Court erred in granting a directed verdict pursuant to Rule 50 of the Federal Rules of Civil Procedure on appellant's theory of negligence. (P. 923, lines 3-5)

POINTS AND AUTHORITIES IN SUPPORT OF SPECIFICATION OF ERROR NO. 4

In the case of *Stromsdot v. Parke-Davis and Company, supra*, the court stated:

"Clinical trials of Quadrigen prior to marketing were conducted by Dr. Clarence D. Barrett of Detroit beginning in 1956 and terminating in 1959. These tests used Quadrigen considered 'fresh' in that the product was less than six months of age from the date of 'pooling' of the polimyelitis component with the DPT fraction. The trials were designed to determine antibody response and the earliest age in infancy at which immunization against poliomyelitis, diphtheria, tetanus and pertussis would be started, using a multiple anti-

gen against all four diseases. No clinical reactions of any serious consequences were reported or observed.

"Quadrigen was then made available to selected members of the medical profession who were requested to comment on their use of the product. These 'field trials' indicated a marked increase in reactions among patients given Quadrigen over those being given DPT and poliomyelitis vaccine. Of the severe reactions reported the first apparent instance in which death resulted was in March of 1959. It does not appear that Parke-Davis made any effort to determine the cause of the high incidence of reactions, and only a cursory attempt was made to investigate the cause of a death attributed to the use of Quadrigen.

"It appears to this Court that adequate tests performed prior to marketing would have disclosed the product's potency instability as well as the cause of greater incidence of reaction, especially in view of the number and seriousness of the reactions being reported. This was not a situation where an epidemic existed or where need justified the risk of premature marketing since products were already available to the medical profession that satisfactorily accomplished what Quadrigen was designed to do."

SPECIFICATION OF ERROR NO. 5

The District Court erred in giving Instruction No. 14 concerning implied warranty to the jury.

INSTRUCTION NO. 14

"In considering the question of breach of an implied warranty, you are instructed that the implied warranty involved in this case is that the vaccine was reasonably fit for the particular purpose for which is was manufactured. In other words, under such circumstances the law imposes upon defendants a warrantly that the Sabin vaccine, which it manufactured and supplied, was reasonably fit and reasonably safe for consumption by members of the public as a whole. This warranty does not mean, however, that this vaccine could be used with absolute safety, but means only that the vaccine must have been reasonably fit and reasonably safe for use by the public as a whole."

POINTS AND AUTHORITIES IN SUPPORT OF SPECIFICATION OF ERROR NO. 5

The Court in *Gottsdanker v. Cutter Laboratories*, 6 Cal.Rptr. 320, had under consideration a verdict returned for the plaintiffs in which the jury drew a statement. In commenting on this statement, Judge Draper stated at page 322:

"In returning its verdicts for plaintiffs, however, the jury drew a thoughtful and careful statement settoing forth that the jury had first considered the issue of negligence, and had 'from a preponderance of the evidence concluded that the defendant, Cutter Laboratories, was not negligent either directly or by inference.'

" 'With regard to the law of warranty, however, we feel that we have no alternative but to conclude that Cutter Laboratories came to market * * * vaccine which when given to plaintiffs caused them to come down with poliomyelitis, thus resulting in a breach of warranty. For this alone we find in favor of plaintiffs.' "

At P. 326:

"Defendant strongly argues that public policy will best be served by denying recovery in warranty for 'new' drugs. The argument is that development of medicines will be retarded if manufacturers are held to strict liability for their defects. While this argument might have merit if the warranty involved had to do with the mere failure of a medicine to cure or of a vaccine to prevent, it seems to be of but little weight where, as here, the warranty is limited to an assurance that the product will not actively cause the very disease it was designed to prevent."

In 1 *Frumer & Friedman Products Liability*, 382.2, Par. 16.03(4), the court stated:

"The manufacturer will be an insurer if, * * * a breach of warranty is proved, i.e., that his product was defective, or injurious, *or failed in normal use.*" (emphasis supplied)

SPECIFICATION OF ERROR NO. 6

The District Court erred in not giving Plaintiff's Requested Instruction No. 23.

"There is an implied warranty under the laws of the State of Montana that one who makes a business of selling drugs for domestic use warrants to one who buys for actual consumption that they are sound and wholesome. This warranty extends to the public generally and the liability of the seller rests upon the principle that his original act in selling impure drugs is unlawful and that he is responsible for the natural consequences of his wrongful act.

"If you find from a preponderance of the evidence that the plaintiff in this case purchased Sabin Type III vaccine from the defendants, and if you find that such vaccine was impure, then the defendants are responsible for the natural consequences of the wrongful act in selling an impure drug to the plaintiff. Under the laws of the State of Montana, even if you find that the defendants sold their product to a third party and the third party sold to the plaintiff, nevertheless, if you find that such product contained an impurity and the impurity was the proximate cause of the plaintiff's present physical condition, then you must find against these defendants in favor of the plaintiff for damages in accordance with these instructions."

POINTS AND AUTHORITIES IN SUPPORT OF SPECIFICATION OF ERROR NO. 6

Gottsdanker v. Cutter Laboratories,
182 Cal.App.2d 602, 6 Cal.Rptr. 320,
79 A.L.R.2d 290

Klein v. Duchess Sandwich Co.,
14 Cal.2d 272, 93 P.2d 799

Peterson v. Lamb Rubber Co.,
14 Cal.2d 339, 4 Cal.Rptr. 863,
353 P.2d 575

Vallis v. Canada Dry Ginger Ale, Inc.,
190 Cal.App.2d 35, 11 Cal.Rptr. 823

Vassallo v. Sabatte Land Co.,
212 Cal. App.2d 11, 27 Cal.Rptr. 814

Jones v. Burgermeister Brewing Corp.,
198 Cal.App.2d 198, 18 Cal.Rptr. 311

Title 27, Ch. 1, including but not
inclusively, 27-117, of the Revised
Code of Montana

Bolitho v. Safeway Stores, Inc.,
109 Mont. 213, 95 P.2d 443

Kelley v. John R. Daily Co.,
181 P. 326, 56 Mont. 63

*Seaton Ranch Co. v. Mont. Vegetable Oil
& Feed Co.*, 252 P.2d 1040
R. C. M., 1947, Sec. 74-321

SPECIFICATION OF ERROR NO. 7

The Plaintiff in this action attempted to elicit information from the Defendant concerning the profit made on the sale of the Sabin Type III vaccine. The

District Court erred in granting Defendants' Objections to Interrogatories No. 8 and 9 dated September 4, 1964.

POINTS AND AUTHORITIES IN SUPPORT OF SPECIFICATION OF ERROR NO. 7

The profit made on the sale of a product is admissible to prove over-promotion with a resulting minimization of any insert warning. *Love v. Wolf,* 226 ACA 482, 38 Cal.Rptr. 183 (Cal.App. 1964) The Court stated:

> "Here it cannot be said that the wealth of Parke-Davis was relevant to any issue. Proof of its sales, however, expressed either in grams or dollars, was relevant to show a motive or reason for the alleged over-promotion of the drug, a definite issue in the case. The determination of whether such relevant evidence is, or should be, admissible is to be made by reference to rules covering the problem of restricted admissibility. We have pointed out above that no absolute special rule of exclusion applies to prohibit proof of dollar sales or profit. Being relevant and not within a rule of absolute exclusion it should be admitted—but only for a proper purpose, and under instructions of the court limiting it to that proper purpose."

SPECIFICATION OF ERROR NO. 8

The District Court erred in sustaining various objections to questions propounded by appellants' counsel during the cross-examination of defendant's agent, James N. Franklin.

POINTS AND AUTHORITIES IN SUPPORT OF SPECIFICATION OF ERROR NO. 8

This subject will be covered in the general argument by citing portions of the transcript of the record.

ARGUMENT

This Court is faced with an issue which no appellate court in the land has ever determined. Undoubtedly, counsel for appellees will argue that a warning to the medical profession concerning a prescription drug is sufficient. The uniqueness of this case lies in the fact that there was no physician-patient relationship between the Plaintiff and any doctor in the State of Idaho. The question this Court must decide is "does a warning to a physician insulate the drug manufacturers from liability when there is no contact between patient and doctor?" The answer to this question must be no.

After the introduction of the Salk vaccine, the incidence of polio rapidly declined. By 1960, polio was not considered a major health hazard in the United States. Doctor Sabin had been investigating the possibilities of a live virus vaccine during the period when polio was considered a major health hazard. For some inexplicable reason a mass immunization program for the entire country was promoted. We do not deny that the Sabin vaccine effectively immunizes one against the disease of polio. It is apparent that health authorities and drug manufacturers wanted to entirely eliminate the disease. By immunizing the vast proportion of the population with the Sabin vaccine, this goal could be

accomplished. The Salk vaccine had one drawback, i.e., it was difficult to obtain the cooperation of a great proportion of the population to have a needle injected into their arms. Tragic as it may seem, the decision was apparently made that for the good of the many, a few should suffer. The Surgeon General's advisory committee repeatedly informed the responsible health officials and the drug companies that there was a risk attendant with the use of the Sabin Type III oral vaccine. Nevertheless, community programs went forward on a mass immunization basis. It is obvious why no warning was disseminated to the general public. The mass immunization goal could not have been reached if a warning was generally disseminated among the population. The Honorable Fred M. Taylor commented on Page 569:

> "I seriously doubt it, but it is not in the case, if any of the promotion that any adult was told at the time that it was given of the risk involved—I doubt if any adult was told."

At page 557, the Court stated:

> "The thing that is bothering the court is who is liable for not telling the man, and giving the man the serum which apparently up to this minute has caused him to be in this terrible shape that he is in."

At page 549, the Court:

> "Let me ask you this: I am not trying to harass you, but the problem bothers me. It is true, I think that the evidence conclusively shows that the man

was not advised and it was not prescribed but he took it, and it was administered by a druggist, and as a result of a campaign that was going on in Eastern Idaho and it slopped over into Montana. Did Wyeth Laboratories administer or have anything to do with the administration of the drug at that time and place that it was administered?"

The Court goes to the nub of the problem in the case. The Court, however, directed a verdict against Plaintiffs on the theory of failure to warn. (P. 923, lines 3-5) The question now becomes "was evidence introduced which could conceivably raise a jury question as concerns failure to warn?" It is appellant's position that the evidence is replete with testimony establishing the fact that the Wyeth representative, Mr. James N. Franklin, actively engaged in promoting this product to the general public. Defendant constantly contended that all Franklin did was sell the product to the medical society and then go about his business selling other Wyeth products. The following testimony is contrary to that position and creates a jury question concerning failure to warn:

Testimony of James N. Franklin:

Page 45
Line 3 "A. Originally it was. Because there is not a physician living in West Yellowstone."

Page 48
Line 14 "Q. Did your company send the books to you?

A. Yes, sir.

Q. And the books were used as a format for conducting mass immunization clinics?

A. That is correct.

Q. And the company gave them to you for that purpose?

A. Yes, sir."

Page 49

Line 15 "Q. And you furnished that to Mr. Tyne, in Pocatello?

A. Yes."

Page 50

Line 2 "Q. With respect to the other book, have you ever seen that book before?

A. It was furnished after the program had started, Mr. Evans."

Page 56

Line 2 "Q. You also made arrangements, did you not, for the vaccine to be delivered by the Jeep Patrol of Idaho Falls?

A. You mean on the distribution?

A. Yes.

A. Yes."

Page 57

Line 4 "THE WITNESS: Did I call and contact the Jeep Patrol unit?

A. Yes.

A. Yes, I did."

Page 59

Line 3 "Q. Did you send some of the cards to West Yellowstone to be used in the campaign?

A. Yes, sir.

Line 20 Q. You had some forms printed, didn't you?

A. Yes. Mr. Tyme had me place his order with the lithographers in Pocatello."

Page 60

Line 15 "Q. Did you arrange for the immunization cards to be sent to West Yellowstone?

A. Yes.

Q. And you arranged for them to be printed by the Pocatello printing company?

A. Yes, sir.

Q. Now, did you also arrange for some posters to be printed at the Pocatello printing company?

A. Yes, I did."

Page 74

Line 24 "Q. And there I asked you this question: (reading) 'Who thought up the idea of doing the posters?' These 'K-O' posters. And the answer is: 'This was suggested in one of the books that they sent. You see, when the society started to go ahead, they send

books to the society which gives suggestions on advertising.' And the question: 'Who sent the books to them?' And the answer: 'Wyeth Laboratories'. And the question: 'I guess through you, you are the one that physically sent them aren't you?' And your answer: 'They came to me and I distributed them, yes.' Question: 'You sent one to each of the medical societies here in Eastern Idaho?' Do you recall that?

A. Yes."

Page 76

Line 16 "Q. Now, did you then have—did the company send you any place for any special training for the holding of the mass immunization clinics?

A. Yes, sir.

Q. Where?

A. Nevada.

A. I believe it was in October of 1962."

It is interesting to note here that all of the above transpired after the medical society had selected the Wyeth product.

Page 80

Line 9 "Q. You actually gave the posters to the man to take to West Yellowstone, did you not?

A. Yes, the ones that went to West Yellowstone, I did; yes."

Page 115

Line 3 "Q. No one in West Yellowstone ordered the vaccine?

A. No, sir.

Q. But you sent it up there, nonetheless?

A. Yes, sir."

Page 116

Line 15 Q. What information did you give Mr. Brower? (the pharmacist in West Yellowstone)

A. Along with the kits that went with the vaccine, an instruction sheet was incorporated telling how to set up the clinics, and how to handle the vaccine, and how to handle the disbursements."

Testimony of Robert M. Brower (pharmacist in West Yellowstone):

Page 169

Line 19 "Q. What did the conversation relate to, Mr. Brower?

A. It related to the 'K-O' polio program which was going to take place in Eastern Idaho and West Yellowstone was going to be included in that program, and Mr. Franklin, we talked about this program, and he wanted to know approximately how many doses—."

Page 170
Line 20 "Q. Who instructed you to send the money to Mr. Simpson?
A. Mr. Franklin."

Testimony of Dr. Willis Melcher:

Page 202
Line 8 "A. He (Mr. James Franklin) told me at that time that he had been instructed by Wyeth Pharmaceutical Company to drop all of his detailing and put all of the time into the management of the 'K-O' polio program."

Testimony of Delmer Edward Simpson:

Page 248
Line 20 "A. These are what we term 'out of pocket expenses' incurred by Mr. Franklin in the promotion of the 'K-O' polio, and its long distance telephone calls, and items that he had purchased, such as sugar, and dry ice, and his participation in the meetings. There is a lunch for the Medical Careers Club of Idaho Falls."

Page 249
Line 25 "A. Yes. It is an invoice from the Pizza Prince Restaurant, Idaho Falls, addressed to the 'K-O' polio, to J. N. Franklin, for 40 spaghetti dinners."

Page 259

Line 11 "A. No one had to okay it, if Mr. Franklin presented it and it appeared to be for legitimate reasons, I wrote the check out.

Q. Would Mr. Franklin have been in a position to hand you a bill and instruct you to pay it?

A. Yes, in many ways, because of the fact that he was the one that brought the invoices from the doctors, or from the managers of the clinics, he was the liaison officer in many cases that brought the invoices."

Page 259

Line 25 "A. Primarily Doctor Fife and myself could sign the checks, and if Mr. Franklin presented a bill that we had no question, he had the authority to ask us to pay it. Mr. Franklin was active in the 'K-O' polio drive, and if he authorized us to pay a bill, we would have."

Page 261

Line 10 "A. That is hard to answer because in the two or three meetings, in one case it was Doctor John Casper, and in Pocatello where I was introduced to the group in Pocatello, I was introduced as the person to take

> care of the funds, I was introduced by Jim Franklin, and he was the chairman of the meeting."

Certainly the above quoted testimony presents a jury question as to whether or not the Defendant Wyeth drug company was in any way connected with the mass immunization programs, and the jury should have been instructed on appellant's failure to warn theory. It was prejudicial error to direct a verdict in appellee's favor.

Doctors Ager, Ravenholt, Johnson and Melcher all testified that the Plaintiff contracted poliomyelitis as a result of taking the Sabin Type III oral vaccine. No competent evidence was introduced to indicate that Davis's condition arose out of any hereditary, predisposition, or congenital factor. This was not an allergic reaction to any drug. This was a defective product which contained live polio virus.

As the Court said in *Gottsdanker v. Cutter Laboratories, supra*, at page 21:

> "Defendant strongly argues that public policy will best be served by denying recovery in warranty for 'new' drugs * * * While this argument might have merit if the warranty involved had to do with the mere failure of a medicine to cure or of a vaccine to prevent, it seems to be of but little weight where, as here, the warranty is limited to an assurance that the product will not actively cause the very disease it was designed to prevent."

Surely there is an implied warranty that Davis would not get polio from the Sabin Type III vaccine.

The Court instructed the jury in Instruction No. 13, page 939:

> "If you find and believe from a preponderance of the evidence that there was such an implied warranty on the part of the defendants as to their vaccine, and you further find that the plaintiff, Glynn Davis, contracted the disease of poliomyelitis as a direct and proximate cause of the ingestion or taking of defendants' vaccine, then defendants would have breached their implied warranty and you should find for the plaintiffs."

Plaintiffs have no argument with this instruction. We feel it is a correct statement of law. However, Instruction No. 14, heretofore set out in full in Specification of Error No. 5, grossly misstates the law as to this particular case. Instruction No. 14 leaves one with the impression that the implied warranty means that it must be reasonably safe for the public as a whole. The implied warranty of fitness does not mean that it will be reasonably safe for the public at large when it causes the very disease it was designed to prevent. This instruction leaves one with the impression that if the statistical number of cases of polio caused by the vaccine is low enough, the vaccine is reasonably fit for the purpose for which it was intended. We feel this is not and should not be the law. If this product caused one case of polio, that individual should be compensated for a breach of the implied warranty of fitness.

The theory of absolute liability should be adopted in cases of this nature. The Plaintiff introduced evidence

that the disease was caused by the vaccine. (P. 442, lines 16-17) The reason the vaccine can cause the disease is because it retains a virulence or pathogenicity. In other words, the vaccine contains live virus capable of producing the disease. (P. 446, lines 8-9) Doctor Bierly, an agent of the Wyeth company, stated at page 611, line 4:

> "Q. Is it supposed to be pathogenic—able to cause polio in an adult?
>
> A. No."

As the Minnesota Court stated in *Schilling v. Roux Distributing Co.*, 266 Minn.71, 59 N.W.2d. 907:

> "The theory upon which the case was tried was that the defendant had warranted the dye to be safe if used in accordance with instructions and that the plaintiff having so used the particular bottle involved herein, nevertheless was injured. * * * * We are committed to the more liberal rule that proof of harmful ingredients in the particular bottle or container causing the harm is not required."

In *Patterson v. George H. Weyer, Inc.*, 189 Kan. 501, 370 P.2d 116, 119, the Court:

> "It was not incumbent upon the plaintiff to produce a chemical analysis of the product or medical testimony showing it poisonous or deleterious. When the application of it to her hair and scalp was followed by symptoms from which the simple and common sense inference would be drawn by the jury that the plaintiff suffered injury, * * * * as a

direct result of an application of the permanent wave."

The Honorable Fred M. Taylor was convinced that the Plaintiff had to point out a defect in the vaccine or a deleterious substance in the vaccine before the theory of absolute liability would apply. At Page 907, the Court:

"I don't recall that anybody—any witness testified that he examined any of this lot of vaccine and found a defect in it. They said, as I remember the testimony, Mr. Evans, that it was caused because of a pathogenic agent. That is the conclusion, or the opinion, and I don't believe that it is worthy of belief. If you get to the defect of the manufacture of something, you have to show the defect in the manufactured article, and you must examine the article."

Line 14:

"THE COURT: I don't think there is a reason to belabor it. If it goes to the jury, it is not on that theory."

We can only repeat again that four doctors, two of whom are nationally recognized specialists in the field of polio, and one of whom was a member of the Surgeon General's committee, testified that the vaccine contained live polio virus which produced the disease in Mr. Glynn Richard Davis.

We respectfully submit that the jury should have been instructed on the theory of absolute liability.

CONCLUSION

This case was tried long and hard by counsel on both sides. The testimony consists of some 957 pages. The Court must instruct on counsel's theory of the case if there is any evidence to substantiate it. We sincerely believe that the Wyeth Laboratories actively promoted this drug to the public with full knowledge that there was a risk involved. That for financial gain they did not warn the public. The company was well aware that persons who lived in rural areas in the Pacific Northwest in a certain socioeconomic group with a poor history of Salk vaccine were candidates for the disease of polio if they ingested the Sabin Type III oral vaccine. Mr. Glynn Richard Davis took their vaccine with no knowledge of the risk and contracted a disease which has paralyzed him for the rest of his life.

We feel the Court committed serious error in limiting the jury to an erroneous interpretation of the law of implied warranty. We feel this case should be reversed.

Respectfully submitted,

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by_____
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by_____
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Attorneys for Appellants

CERTIFICATE OF ATTORNEY

I certify that, in connection with the preparation of this brief, I have examined Rules 18 and 19 of the United States Court of Appeals for the Ninth Circuit, and that, in my opinion, the foregoing brief is in full compliance with those rules.

ELAM, BURKE, JEPPESEN & EVANS

by_____

Robert J. Koontz

Attorney for Appellants

TABLE OF EXHIBITS

Defendants' Exhibits		for Identification	in Evidence
No. 40	Vaccine kit		105
No. 49	AMA report	211	
No. 50	Dr. Barrows' report	225	226
No. 43	"Viral and Rickettsial Infections of Man"		
No. 51	AMA article	237	
No. 63	Surveillance report		465
No. 75	Dr. Horstmann's report	580	
No. 76	Surveillance report	591	592
No. 77	Surveillance report	591	592
No. 58	Surveillance report		590
No. 59	Surveillance report		590
No. 60	Surveillance report		590
No. 61	Surveillance report		590
No. 62	Surveillance report		590
No. 64	Surveillance report		590
No. 65	Surveillance report		590
No. 66	Surveillance report		590
No. 67	Surveillance report		590
No. 68	Surveillance report		590
No. 44	Defendant's protocol	623	
No. 78	Test results	649	650
No. 45	Shipping record		653
No. 79	Photograph	770	774
No. 52	Press release	770	771
No. 53	Report	816	
No. 54	Report	816	
No. 55	Report	816	
No. 56	Report	816	
No. 74	Surveillance report		886
No. 16	Letter		898